K130230



ATTACHMENT 002

## 510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: Oct. 17.2013

### 1. Submitter Name and Address:

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NOV 2 0 2013

### 2. Submission Devices Information:

Trade/Proprietary Name:
1. Sterile Piston Hypodermic Syringes (With/Without Needle).
2. Hypodermic Needles.

Common Name:
1. Piston Syringe
2. Hypodermic Needle.

Classification name:
1. Piston Syringe.
2. Hypodermic Single Lumen Needle.

Class:
1. II.
2. II.

Panel:
1. 80.
2. 80.

008

Procodes:

1. FMF - Piston Syringe and FMI - Hypodermic Single Lumen Needle
2. FMI - Hypodermic Single Lumen Needle

## 3. Predicate Devices Information:

1. Piston Syringe:
   Trade Name: BD Single Use, Hypodermic Syringe
   510(K) Number: K110771
2. Hypodermic Needle:
   Trade Name: BD Hypoint™
   510(K) Number: K070440

## 4. Devices Description:

### 4.1 Sterile Piston Hypodermic Syringes (With/Without Needle).

The piston syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male Luer Slip/Lock connector (nozzle) for attaching the female Luer connector (hub) of a hypodermic single lumen needle, or for attaching other devices with a female Luer. The syringe is sterilized by EtO gas. And it is a Non-Pyrogenic and single use device. The mainly raw materials are PP, PE and rubber.

| Ref Number | Model Number | Description | Size |
|---|---|---|---|
| YSPS001 | YSPS | Piston syringe with/without needles | 0.5cc/ml≤Capacity of Syringe<2cc/ml |
| YSPS002 | YSPS | Piston syringe with/without needles | 2cc/ml≤Capacity of Syringe<5cc/ml |
| YSPS003 | YSPS | Piston syringe with/without needles | 5cc/ml≤Capacity of Syringe<10cc/ml |
| YSPS004 | YSPS | Piston syringe with/without needles | 10cc/ml≤Capacity of Syringe<20cc/ml |
| YSPS005 | YSPS | Piston syringe with/without needles | 20cc/ml≤Capacity of Syringe<30cc/ml |
| YSPS006 | YSPS | Piston syringe with/without needles | 30cc/ml≤Capacity of Syringe<50cc/ml |
| YSPS007 | YSPS | Piston syringe with/without needles | 50cc/ml≤Capacity of Syringe |

### 4.2 Hypodermic Needles.

The Hypodermic Needle is a single lumen needle, designed for use with syringes and injection devices for general purpose fluid injection. The needle is sterilized by EtO gas. and it is a Non-Pyrogenic and single use device. The mainly raw materials are PP and stainless steel.

| Ref | Model | Description | Length | Gauge |
|---|---|---|---|---|

| Number | Number | | | |
|---|---|---|---|---|
| YSHN001 | YSHN | Hypodermic Needle Normal-walled | 1/2 to 1" | 30G |
| YSHN002 | YSHN | Hypodermic Needle Normal-walled | 1/2 to 1" | 29G |
| YSHN003 | YSHN | Hypodermic Needle Normal-walled | 1/2 to 1" | 28G |
| YSHN004 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 27G |
| YSHN005 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 26G |
| YSHN006 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 25G |
| YSHN007 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 24G |
| YSHN008 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 23G |
| YSHN009 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 22G |
| YSHN010 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 21G |
| YSHN011 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 20G |
| YSHN012 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 19G |
| YSHN013 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 18G |
| YSHN014 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 17G |
| YSHN015 | YSHN | Hypodermic Needle Normal-walled | 1 to 1 1/2" | 16G |

## 5. Intended Use:

### 5.1 Sterile Piston Hypodermic Syringes (With/Without Needle).

Sterile Piston Hypodermic Syringes (With/Without Needle) is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.

### 5.2 Hypodermic Needles.

The hypodermic needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe.

## 6. Technological Characteristics:

Through comparisons between the applicant devices with the predicate devices as follows tables. We believe the applicant devices are substantially equivalent with the predicate devices.

### 6.1 Sterile Piston Hypodermic Syringes (With/Without Needle) Comparison Table

| Element of Comparison | Submission Device | Predicate Device K110771 |
|---|---|---|
| **Intended Use** | Sterile Piston Hypodermic Syringes (With/Without Needle) is a device intended for medical purposes that consists of a calibrated hollow barrel and a | The BD Single Use, Hypodermic Syringe is intended for use by health care professionals for general purpose fluid aspiration/ |

| | | |
|---|---|---|
| | movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body. | injection. |
| **Principle of Operation** | Normal | Normal |
| **Syringe Capacity** | Various Sizes | Various Sizes |
| **Nozzle Type** | Luer | Luer |
| **Lubricant for Barrel** | Silicone Oil | Silicone Oil |
| **Barrel Transparency** | Transparent and Clear | Transparent and Clear |
| **Gradations Legibility** | Legible | Legible |
| **Needle Gauge and Length** | Various Sizes | Various Sizes |
| **Lubricant for Needle** | Silicone Oil | Silicone Oil |
| **Materials** | | |
| **Barrel** | PP | PP |
| **Plunger** | PE | PE |
| **Piston** | Rubber | Rubber |
| **Nozzle Cap** | PE | PE |
| **Needle Hub** | PP | PP |
| **Needle** | Stainless Steel | Stainless Steel |
| **Performances** | Conforms to ISO7886-1 | Conforms to ISO7886-1 |
| **Biocompatibility** | Conforms to ISO10993 | Conforms to ISO10993 |
| **Labeling** | Meet the requirements of 21 CFR Part 801 | Meet the requirements of 21 CFR Part 801 |

## 6.2 Hypodermic Needles Comparison Table

| Element of Comparison | Submission Device | Predicate Device K070440 |
|---|---|---|
| **Intended Use** | The hypodermic needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe. | The BD Hypoint™ Hypodermic Needle is intended for use with Syringes and injection devices for general purpose fluid aspiration/ injection. |
| **Principle of Operation** | Normal | Normal |
| **Needle Gauge and Length** | Various Sizes | Various Sizes |
| **Lubricant for Needle** | Silicone Oil | Silicone Oil |
| **Materials** | | |
| **Needle Hub** | PP | PP |
| **Needle** | Stainless Steel | Stainless Steel |
| **Needle Sheath** | PE | PE |
| **Performances** | Conforms to ISO7864 | Conforms to ISO7864 |
| **Biocompatibility** | Conforms to ISO10993 | Conforms to ISO10993 |
| **Labeling** | Meet the requirements of 21 CFR Part 801 | Meet the requirements of 21 CFR Part 801 |

## 7. Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent.
Our device and the predicate device are same in intended use, Essential Component, Material, Sterile, Function etc.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2013

Wuxi Yushou Medical Appliances Company, Limited
C/O Garfield Wang
Regulatory Associate
215 No. Xigang Road,
Dongbeitang Wuxi City
Jiangsu, China 21491

Re: K130230
Trade/Device Name: Sterile Piston Hypodermic Syringes (With/Without Needle) and Hypodermic Needles
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF/FMI
Dated: October 18, 2013
Received: October 21, 2013

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S

for

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K130230

Device Name
Sterile Piston Hypodermic Syringes (With/Without Needle)

Indications for Use *(Describe)*
Sterile Piston Hypodermic Syringes (With/Without Needle) is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from the body.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA
Digitally signed by
Richard C. Chapman
Date: 2013.11.19
13:00:19 -05'00'